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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR       | ATTORNEY DOCKET NO.              | CONFIRMATION NO.       |
|--|-------------|----------------------------|----------------------------------|------------------------|
| 10/541,501   | 07/07/2005  | Phaedria Marie St. Hilaire | ST.HILAIRE1A                     | 4075                   |
| 1444 7590 09/16/2008<br>BROWDY AND NEIMARK, P.L.L.C.<br>624 NINTH STREET, NW<br>SUITE 300<br>WASHINGTON, DC 20001-5303 |             |                            | EXAMINER<br>WESSENDORF, TEREŠA D |                        |
|  |             |                            | ART UNIT<br>1639                 | PAPER NUMBER           |
|  |             |                            | MAIL DATE<br>09/16/2008          | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



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BROWDY AND NEIMARK, P.L.L.C.  
624 NINTH STREET, NW  
SUITE 300  
WASHINGTON, DC 20001-5303

In re Application of: :  
St. Hilaire et al. :  
Serial No.: 10/541,501 : PETITION DECISION  
Filed: July 07, 2005 :  
Attorney Docket No.: ST.HILAIRE1A :

This is in response to the petition filed August 7, 2008, presumably under 37 CFR § 1.181, requesting that the finding of non-responsiveness by the examiner as communicated in the letter of June 11, 2008 be overturned in favor of applicants.

BACKGROUND

The examiner mailed a non-final Office action November 7, 2007. At the time this Office action was mailed, claims 3, 4, 6-7, 16, 22, 26, 29-31, 35-36, 43, 44, 46, 49, 50, 77, 78 and 88-90 were pending and claims 3, 4, 6, 7, 16, 22, 26, 29-31, 35, 36, 46, 49, 50, 77, 78, 89 and 90 were withdrawn from examination on their merits as being directed toward a non-elected species of Invention, leaving claims 43, 44 and 88 to be examined. In this Office action, *inter alia*, the examiner instituted a rejection of claims 43 and 90 under 35 U.S.C. § 112, first paragraph, for lacking written description, rejected claims 43, 88 and 90 under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, rejected claim 88 under 35 U.S.C. 102 (b) as being anticipated by or, in the alternative, under 35 U.S.C. 103 § (a) as obvious over St. Hilaire et al. (1998), as well as Lohse (US 6,602,685). The examiner also rejected claim 88 under 35 U.S.C. 102 (a) as being anticipated by Tomlinson et al. (US 2002/0115068). The examiner objected to claim 44 for being dependent upon a rejected base claim and indicated that claim 44 would be allowable if rewritten in independent form. Here, there is some confusion to what claims were actually examined. The PTOL-326 form which accompanied the non-final Office action indicates that claims 43, 88 and 90 were rejected, and claim 44 was objected to. However, the PTOL-326 form also indicates that claim 90 was withdrawn from consideration. Since claims

43, 88 and 90 were rejected, and claim 44 was objected to, it appears that claims 43, 44, 88 and 90 were, in fact, examined.

On March 6, 2008, in reply to the non-final Office action of November 7, 2007, applicants submitted remarks and arguments as well as amendments to claims 43, 44, 46 and 89, and presented new claims 91-101.

On June 11, 2008 the examiner mailed a letter to applicants indicating that their response filed on March 6, 2008 was non-responsive to the non-final Office action mailed November 7, 2007. In this non-responsive letter, the examiner specifically stated:

The reply filed on 3/6/08 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s): the amendments to the claims which added new claims and amended e.g., claim 43 is non-responsive. The added claims also introduce new subject matter that has not been considered and examined before. For example, the prior Office action indicated the allowability of the elected species, HY6. However, the amendments to generic claim 43, for example, were such that the additional limitations introduced new subject matter not corresponding with the indicated allowable subject matter. The 35 USC 112, second paragraph rejection regarding the used *[sic]* of the Tables in the claims introduced compounds such as protecting groups, which are not amino acids, *[sic]* are non-responsive amendments. Applicants used *[sic]* of the Tables is not an "exceptional case" as clearly the Tables recite each of the naturally occurring amino acids, for example. See 37 CFR 1.111. Also several independent claims for which no fees have been filed had been introduced in the present amendments. See MPEP 714.10. Since the above-mentioned reply appears to be bona fide, applicant is given ONE (1) MONTH or THIRTY (30) DAYS from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a)

In response thereto, applicants filed this petition on August 7, 2008, presumably under 37 CFR § 1.181, requesting that the finding of non-responsiveness by the examiner as communicated in the letter of June 11, 2008 be overturned in favor of applicants.

It is noted that applicants additionally filed an amendment with remarks on August 7, 2008.

## DISCUSSION

The petition and the file history have been carefully considered.

In the petition filed on August 7, 2008, applicants requested relief from the examiner's refusal to resume prosecution of this case. Specifically, applicants argue that the non-responsive letter mailed on June 11, 2008 was improper, and contend that the amendment submitted on March 3, 2008 was sufficient to appropriately respond to the non-final Office action mailed on November 7, 2007:

The test for whether an amendment is fully responsive to a nonfinal action is whether it (1) substantially responds to each rejection, objection and requirement, and (2) is a bona fide attempt to advance the case to final action. See MPEP 714.03. The applicant need not adopt the examiner's suggestion for amending the claims to overcome a particular rejection or objection; the applicant may instead contend that the rejection or objection is wrong as a matter of law or inappropriate in view of the particular facts. The applicant may add claims, or amend claims, even if that might raise new issues, so long as the applicant has responded, at least by argument, to all outstanding issues.

Hence, the holding of non-responsiveness should be vacated and the case returned to the examiner for the preparation of a new action on the merits.

#### Applicants' arguments continue:

...the amendment to claim 43 was actually a narrowing amendment, as the now-eliminated dependency on 88 didn't structurally limit the ligand, and we limited the allowed amino acids to those of tables 1, 2, 3, 7 and 9...even if claim 43 had been amended to include previously unclaimed subject matter, such an amendment is allowed as of right, provided that there has been no final rejection or Ex parte Quayle action...MPEP 714.19(A) and 714.20(C). The Examiner can limit examination of the amended claim to the elected species, but can't refuse to enter the amendment. Amendments in a nonfinal case, which comply with formalities...are entered as a matter of right. See MPEP 714(I)(A).

#### 37 C.F.R. 1.111 (b) states:

In order to be entitled to reconsideration or further examination, the applicant or patent owner must reply to the Office action. The reply by the applicant or patent owner must be reduced to a writing which distinctly and specifically points out the supposed errors in the examiner's action and must reply to every ground of objection and rejection in the prior Office action. The reply must present arguments pointing out the specific distinctions believed to render the claims, including any newly presented claims, patentable over any applied references. If the reply is with respect to an application, a request may be made that objections or requirements as to form not necessary to further consideration of the claims be held in abeyance until allowable subject matter is indicated. The applicant's or patent owner's reply must appear throughout to be a bona fide attempt to advance the application or the reexamination proceeding to final action. A general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references does not comply with the requirements of this section.

Applicants' response submitted on March 6, 2008 is fully responsive to the non-final Office action mailed by the examiner on November 7, 2007 because said response specifically replied to every objection and rejection instituted by the examiner in the non-final Office action. Thus, the reasons set forth in the letter for holding the reply submitted by applicants filed on March 6, 2008 non-responsive were in error. As correctly pointed out by applicants in the petition of August 7, 2008, claim 43 was merely narrowed to include certain amino acids which does not depart from the scope of claim 44 which was determined, by the examiner in the non-final Office action as being allowable. The amendment to claim 43 by applicants was in-part, an attempt to overcome the rejection of claim 43 made by the examiner under 35 U.S.C. 112, first paragraph. While the examiner indicated in the non-final Office action that claim 44 was objected to, but allowable, applicants are not required in response to the non-final Office action to acquiesce to the examiner's initial proposal of allowance by rewriting claim 43 to include only the examiner's identified allowable subject matter of claim 44. On the contrary, the record of this case

establishes that the election of species instituted by the examiner was set forth over the Markush group of potential embodiments of species present in claim 43. Applicants specifically elected the species of HY6 for examination in the response filed August 27, 2007. With regard to examination of Markush claims upon instituting an election of species, the MPEP § 803.02 states:

*...should the examiner determine that the elected species is allowable, the examination of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The examination will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action can be made final unless the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p). See MPEP § 706.07(a). (emphasis added)*

Newly amended claim 43 should be fully examined on its merits. Should claim 44 still be deemed allowable in the examiner's opinion, the search of the Markush group of claim 43 should be extended to non-elected species of claim 43 as a matter of right, according to the MPEP § 803.02. Accordingly, any new claims presented by applicants in the response submitted on March 6, 2008 which are directed toward the species chosen for examination should be joined with the chosen species and those claims which are not specifically directed toward the species newly chosen by the examiner may be withdrawn from consideration on their merits.

The examiner further stated in the non-responsive letter of June 11, 2008 that "[t]he 35 USC 112, second paragraph rejection regarding the used [*sic*] of the Tables in the claims introduced compounds such as protecting groups, which are not amino acids, are non-responsive amendments." However, applicants' amendment to insert limitations which read on tables is not in itself non-responsive considering that applicants have fully responded to the non-final Office action mailed November 7, 2007. It is plainly evident that applicants responded to the examiner's rejection of claim 90 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph by rebutting said rejection (see p. 15, Remarks of March 6, 2008). Additionally, it can be seen in an amendment filed by applicants on August 7, 2008, subsequent to the filing of the Petition, that applicants have amended claims 43 and 90 to specifically recite species of ligands, hence rendering any point relating to the reference to tables in the claims moot.

It is decided that applicants' response filed March 6, 2008 is fully responsive because the reply satisfies the provisions of 37 C.F.R. 1.114 by specifically responding to each individual rejection set forth by the examiner in the non-final Office action mailed on November 7, 2007. It is noted that applicants are not precluded from submitting arguments in traversal of rejections rather than acquiescing to the examiner's initial findings of rejection by amending the claims. As a matter

of right, applicants are permitted, in lieu of making specific claim amendments, to traverse the examiner's finding of rejection as they deem appropriate.

Considering that applicants' response submitted March 3, 2008 was fully responsive to the non-final Office action of November 7, 2007, the Non-responsive letter mailed by the examiner on June 11, 2008 is hereby VACATED. Accordingly, any formal or informal matters relating to the claims or any matters relating to the merits of the claims may be addressed in a subsequent Office action by the examiner.

## DECISION

The petition is **GRANTED**.

This application will be forwarded to the examiner to act on the amendment submitted on March 6, 2008 and to consider applicants' arguments presented therein. Because the reply submitted on March 6, 2008 was fully responsive to the non-final Office action mailed November 7, 2007, the reply filed August 7, 2008 should be treated as a supplemental response to be acted on by the examiner as well.

Should there be any questions about this decision please contact Marianne C. Seidel, by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0584 or by facsimile sent to the general Office facsimile number, 703-872-9306.



George Elliott  
Director, Technology Center 1600